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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* MEI WEI, JAMES R. OLSON, and  
MONTGOMERY T. SHAW

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Appeal 2015-004558  
Application 11/790,345  
Technology Center 1700

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Before ADRIENE LEPIANE HANLON, LINDA M. GAUDETTE, and  
DONNA M. PRAISS, *Administrative Patent Judges*.

PRAISS, *Administrative Patent Judge*.

DECISION ON APPEAL<sup>1</sup>

A. STATEMENT OF THE CASE

This is a decision on appeal under 35 U.S.C. § 134 from an Examiner's decision rejecting claims 1–19 and 45–56, which are all of the pending claims. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

The subject matter on appeal relates to biomaterials for bone replacement, particularly a mineral polymer composite. Spec. ¶ 2.

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<sup>1</sup> In this decision, we refer to the Specification filed April 25, 2007 (Spec.), the Non-Final Office Action appealed from, mailed December 2, 2013 (Non-Final Act.), the Appeal Brief, filed September 15, 2014 (Br.), and the Examiner's Answer, mailed January 13, 2015 (Ans.).

Polymers are described in the Specification as having “relatively poor mechanical properties” and “poor surface continuity.” *Id.* ¶ 8. The composite is described as including biodegradable polymer fibers that can be coated with a thin layer of calcium phosphate and braided to fabricate sutures. *Id.* ¶ 14. The braids are described as being coated with a layer of low-melting temperature biodegradable polymer and compression molded or woven or knitted to form sheet-shaped composites. *Id.*

Claim 1, reproduced below, is illustrative of the subject matter on appeal.

1. A bone-repair composite, comprising:
  - a fibrous bone replacement composite comprising a multitude of fiber bundles, each bundle comprising:
    - a core, the core being a first primary unit including a combination of a first set of yarns coated with a calcium phosphate mineral layer comprising between 25% by weight and 43% by weight of the fibrous bone replacement composite, the first set of yarns being made from a first group of one or more polymers; and
    - a sheath, the sheath being a second primary unit including a combination of a second set of yarns or one or more polymer coatings the second set of yarns being made from a second group of one or more polymers; and
    - a polymer matrix to bind the multitude of fiber bundles together, the polymer matrix comprising a polymer from the second set of one or more polymers.

Br. 22 (Claims App.).

The Appellants<sup>2</sup> seek review of the Examiner's rejection of claims 1–19 and 45–56 under 35 U.S.C. § 103(a) as unpatentable over Koyfman.<sup>34</sup>

We sustain this rejection for substantially the same reasons set forth in the Examiner's Answer and Non-Final Office Action and add the following for emphasis.

B. DISCUSSION

1. Claim 1

The Examiner finds Koyfman teaches a “composite suture comprising a core made from a bioabsorbable polymer wherein the core is covered by a braided sheath yarn” as required by claim 1. Ans. 4. The Examiner also finds that Koyfman “does not specifically disclose that the first set of yarns is coated with a calcium phosphate mineral layer” but does disclose that “the suture contains active agents that can include pharmaceutical compositions and bone-inducing compositions wherein the bone inducing compositions can include tricalcium phosphate and calcium hydroxyapatite (see paragraph 0032)” and that “[a] coating on the core containing a first set of yarns allows the releasing of active components to the sutures (see paragraph 0013).” *Id.* at 5. The Examiner concludes that “[i]t would have been obvious to one of ordinary skill in the art for the core to be coated with a calcium phosphate mineral layer in order to provide a therapeutically effective dose to the

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<sup>2</sup> The real party in interest is identified by Appellants as Teleflex Medical Incorporated. Br. 3.

<sup>3</sup> Koyfman et al., US 2005/0149118 A1, published July 7, 2005 (“Koyfman”).

<sup>4</sup> In the Answer, the Examiner withdrew the rejection of claims 1–19 under 35 U.S.C. § 112(b). Ans. 6.

suture (see paragraph 0033).” *Id.* The Examiner also finds that the requirement in claim 1 that the calcium phosphate mineral layer comprises “between 25% by weight and 43% by weight of the fibrous bone replacement composite” is optimizable and would have been obvious in view of Koyfman’s disclosure that the amount of active agent affects the therapeutic dose. *Id.* at 6.

There is no dispute on this record that (1) Koyfman discloses a core and sheath made of polymeric yarns, (2) Koyfman discloses a calcium phosphate mineral layer containing tricalcium phosphate, (3) Koyfman discloses the amount of active agents (e.g., tricalcium phosphate) affects the therapeutic dose, and (4) that the “calcium phosphate mineral layer comprising between 25% by weight and 43% by weight of the fibrous bone replacement composite” recited in claim 1 is an optimizable feature. Br. 9–12. The issue in this appeal is whether “modifying the suture of Koyfman to have the calcium phosphate layer weight as recited in claim 1 would essentially change the very principle of operation of such a suture such that the teaching of Koyfman is not sufficient to render the claims *prima facie obvious*.” *Id.* at 10–11.

Appellants argue that “Koyfman discloses only examples of sutures that are 100 wt % polymer.” Br. 10. Appellants contend that “[w]hile Koyfman does mention a variety of active agents that may be used to coat the suture in paragraph [0032], one of ordinary skill would understand these coatings are present in extremely low concentrations.” *Id.* Because Koyfman discloses controlling coating levels to maintain knot security in paragraph 36, Appellants argue that “modifying the suture of Koyfman to

have the calcium phosphate layer weight as recited in claim 1 would essentially change the very principle of operation of such a suture . . . .” *Id.* at 10–11.

The Examiner responds that (1) “[b]eing knotted is not the only intended purpose of the Koyfman sutures” as Koyfman describes a surgical knot as being optionally applied to the suture, (2) “appellant has not provided any evidence to support the position that a fibrous bone replacement composite at between 25-43% by weight is not pliable or capable of being knotted[,]” and (3) “Appellant’s claims 1 and 45 do not require a high amount of calcium phosphate but rather require that the calcium phosphate layer, which can include other ingredients, as a whole make up 25-43% of the composite.” Ans. 7.

As pointed out above, there is no dispute that the coating disclosed in Koyfman includes the tricalcium phosphate component (Koyfman ¶ 32) specifically disclosed in the Specification (Spec. ¶ 15) for the calcium phosphate compound layer. There also is no dispute that Koyfman discloses the amount of active agent used in the coating is sufficient to provide a therapeutically effective dose (Koyfman ¶ 33).

Appellants’ argument fails because it is not supported by the evidence of record. The Examiner’s finding that a surgical knot is optionally applied to Koyfman’s suture is supported by the evidence. Koyfman ¶ 10.<sup>5</sup> We recognize that Koyfman does not disclose a specific weight percent of the

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<sup>5</sup> The Examiner’s finding that a surgical knot is an optional use for a suture is further supported by Appellants’ Specification which also describes a suture as one embodiment. Spec. 6:1.

coating, but the Examiner's finding that Koyfman teaches modifying the amount of active agent used in the coating to achieve a therapeutically effective dose is supported by the evidence. *Id.* at 33. Therefore, the disclosure of Koyfman is not limited to a knotted suture embodiment or coatings present "in extremely low concentrations" as Appellants contend (Br. 10). Moreover, there is no evidence in this record to support Appellants' argument that a phosphate layer between 25% and 43% by weight of the composite would be incompatible with a suture (Br. 10–11). *See In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997) (argument by counsel cannot take the place of evidence)

In sum, the preponderance of the evidence supports the Examiner's conclusion of obviousness. Therefore, the § 103(a) rejection of claim 1 is sustained.

2. Claim 45

Claim 45 is similar to independent claim 1 and additionally recites that the first set of yarns include poly(L-lactic) acid polymer fibers, the polymer matrix comprises a poly( $\epsilon$ -caprolactone) polymer, and "the bone-repair composite being a load bearing structure having a bending modulus of at least 3 Giga Pascals (GPa)." Br. 26 (Claims App.).

Regarding the recited bending modulus, the Examiner finds that Koyfman teaches that "the strength of the composite is based on the ratio of sheath to core." Non-Final Act. 5 (citing Koyfman ¶ 4 ("it is desirable to use materials that will provide high tensile strength")). The Examiner also finds that "Paragraph 0076 of Koyfman discloses improved bending strength. Therefore, it would have been obvious to one of ordinary skill to

have the suture of . . . Koyfman have a bending modulus of at least 3 GPa for improved bending strength.” *Id.* at 9.

The Appellants argue that the Examiner erred because:

[A] person of ordinary skill in the art would not have the motivation to modify Koyfman as suggested by the Examiner to produce a bone-repair composite having a bending modulus similar to bone because Koyfman is directed to a suture that is intended to be tied in a knot to facilitate securing the suture and it is not possible to tie a knot in a bone-like material.

Br. 15.

The Examiner responds that Koyfman discloses that the surgical knot in the suture is optional. Ans. 8. The Examiner further finds that modifying the tricalcium phosphate coating on the core yarns in Koyfman would not “teach away from the intended purpose of . . . Koyfman” because Koyfman teaches improved bending strength in paragraph 76 and also includes as an active in coatings calcium hydroxyapatite, which is found in mammalian bone. *Id.*

As discussed above in connection with claim 1, the record supports the Examiner’s findings that Koyfman teaches optionally applying a knot to the suture as well as modifying the amount of active agents in a coating to provide a therapeutically effective dose. Koyfman ¶¶ 10, 33. The record also supports the Examiner’s finding that Koyfman teaches improved bending strength. Koyfman 76 (“better bending stiffness”); *see also* Koyfman ¶ 78 (“The sutures of the present invention have many advantages. The advantages include . . . high tensile strength . . .”). Appellants do not

identify any error in the Examiner's findings regarding Koyfman's teachings of improved bending strength and effective dose.

Based on the foregoing, the preponderance of the evidence supports the Examiner's conclusion of obviousness. Therefore, the § 103(a) rejection of claim 45 is sustained.

3. Dependent Claims 2–19 and 46–56

Regarding dependent claims 2–19 and 46–56, Appellants rely on the same arguments regarding being able to tie Koyfman's suture into a knot and achieving the claimed mechanical strength of the bone-repair composite. Br. 16–21. Appellants further assert that Koyfman does not teach cold compression molding the suture or using a solvent to melt the sheath because doing so would render Koyfman's suture unusable for its intended purpose. Br. 18–19, 20–21.

Regarding the additional argument, the Examiner responds “[s]ubjecting the bone repair composite to processing steps do[es] not render the claimed bone repair composite patentable over the composite of Koyfman.” Ans. 9.

In the absence of any argument in the record to show that the cold compression and solvent limitations structurally distinguish the claimed composite from the composite taught by Koyfman, we agree with the Examiner.

Therefore, the § 103(a) rejection of claims 2–19 and 46–56 are also sustained for the same reasons discussed above and in the Examiner's Non-Final Office Action and Answer.

Appeal 2015-004558  
Application 11/790,345

C. DECISION

The decision of the Examiner is *affirmed*.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED